



WISCONSIN REGULATORY DIGEST

Volume 10, No. 2 A Publication of the PHARMACY EXAMINING BOARD SEPTEMBER, 1998

Technician Supervision

May a hospital pharmacy technician work under the supervision of a registered nursing supervisor when a pharmacist is absent from work (e.g. illness)? Pharmacists are allowed to delegate certain responsibilities [Pharm. 7.01(1)(c)] to a technician but are not allowed to delegate to another professional (e.g. registered nurse) their responsibility to verify the accuracy of the technician's actions, thus the technician is not allowed to work if a pharmacist is not present. In the absence of a pharmacist, the hospital would be expected to function under the same policy and procedure the institution has for procuring medications after-hours when the pharmacy is closed.

THE WISCONSIN PHARMACY EXAMINING BOARD

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Out-of-State Pharmacies - Quantity Limits

Wisconsin Administrative Code Phar 8.05(1)(5) does not allow a quantity exceeding a 34-day supply of a controlled substance (except up to a 90 day supply of a schedule III or IV anticonvulsant) to be dispensed by a pharmacy in this state. Out-of-state pharmacies are allowed to mail larger days supply of controlled substances to patients in Wisconsin if the state in which the pharmacy is licensed allows it. The Pharmacy Examining Board does not have the statutory authority to license out-of-state pharmacies at this time. The Board will be asking a legislator to introduce legislation this fall that will allow the PEB to license and thus regulate out-of-state pharmacies. The Board encourages any pharmacists interested in helping with the passage of this legislation to contact the Board in writing. In 1994, the United States Postal Service rescinded its regulation that did not allow the use of mail to deliver prescriptions that contained narcotics, thus any prescription drug can be mailed to patients through the U.S. mail.

Confidentiality of Patient Health Care Records

The Board has reviewed several examples of "programs" offered by manufacturers, wholesalers, and buying groups that involve the release of information from prescriptions for various purposes,

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such as patient compliance reminder letters and market share rebates. Pharmacists are encouraged to

review Wisconsin Statute 146.82 before making a commitment to any of these types of programs. It states "Patient health care records may be released only to the persons designated in this section or to other persons with the informed consent of the patient or of a person authorized by the patient." The release of a patient's name, address and/or social security number with any prescription information without the patient's consent would be considered a violation of this statute by the Board.

Change of Dosage Form

There are many cases in which a different dosage form than prescribed is needed in light of a patient's condition. For example a cancer patient with mouth sores may not be able to ingest capsules or tablets, thereby making a liquid dosage form of the medication necessary for appropriate patient care. In reviewing this issue, the presumption is that the dosage form prescribed is to be that dispensed. However, when it is clear that the patient is unable to administer the dosage form prescribed, then the Board believes that the pharmacist may use professional judgment. Accordingly, it is recommended that in situations in which the prescriber is not available to specifically authorize the change in dosage form, the pharmacist may do so in circumstances the pharmacist believes are consistent with the patient's needs. However, a change in dosage form needs to be subsequently communicated to the prescriber so that he or she is aware of the change, and must be documented on the prescription order received. Under no circumstances, could the route of administration be changed.

Preprinted Prescription Pads

The Board asks pharmacists to review Phar 10.03(15), which states that furnishing a prescriber with any prescription order blanks imprinted with the name of a specific pharmacist or pharmacy constitutes unprofessional conduct. The PEB has recently had several cases that are a violation of the rule.

1997 Wisconsin Act 68

This legislation will allow pharmacies to administer adult vaccines pursuant to a written protocol with a physician and after completing a 12 hour training course. Secondly, pursuant to rules to be adopted by the PEB, pharmacists may administer drug products and devices in the course of teaching self-administration techniques to a patient. Finally, beginning with the biennial renewal of a pharmacist's license on June 1, 2000, proof that 30 hours of ACPE-approved continuing education has been completed since June 1, 1998 will be

required. Pharmacists are advised to accumulate documentation of having completed this continuing education.

Pending Rule Changes

On March 10, 1998 a public hearing was held on proposed changes to Wisconsin Administrative Code Phar 1 to Phar 14. These new and revised rules have been sent to the legislative standing committees for their review. When they are returned, the Board will act on them for final adoption.

Included in these rule changes will be the formal adoption of the federal authorization and requirements for prescription orders transmitted by facsimile machine. The Board has had questions specifically concerning the faxing of Schedule II prescriptions. The new rules will allow a Schedule II prescription order to be transmitted by facsimile machine in the following situations:

1. The order is written for a Schedule II controlled substance that is to be compounded for the direct administration to a patient by parental, intravenous, intramuscular, subcutaneous or intraspinal infusion, and is transmitted by the practitioner or the practitioner's agent to the home infusion pharmacy.
2. The order is written for a Schedule II controlled substance for a patient in a long term care facility, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy.
3. The order is written for a Schedule II controlled substance for a patient in a hospice certified by Medicare under Title XVIII or licensed by the state, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy. The definition of "a hospice certified by Medicare under Title XVIII or licensed by the state" has been recently clarified by the DEA to include patients in a hospice program that continue to reside in their residence. The PEB will use this same definition in the enforcement of this rule. The new rule requires that the prescription order indicate that the patient is in hospice. If the prescribing practitioner has failed to write that information on the order, the pharmacist may verify that fact by telephone and add that documentation to the faxed Schedule II prescription.

The prescription order transmitted by facsimile will be considered the original written prescription order and the practitioner will not need to forward a

written order as is done with an emergency Schedule II prescription. It is assumed that the original written prescription order produced by the practitioner for the purposes of faxing remains part of the patient's chart or medical record at the practitioner's office, the long term care facility or hospice.

Food and Drug Administration Modernization Act (Public Law 105-115)

This federal legislation becomes effective November 21, 1998, and sets forth the conditions under which pharmacist compounding will not be considered to constitute manufacturing. The law allows for the compounding of drug products for identified individual patients based on the unsolicited receipt of a prescription authorized by the prescriber. The compounding of a product may also take place prior to the receipt of a valid prescription order based on a history of having received prescription orders for such products within an established pharmacist-patient or pharmacist-physician relationship.

The legislation also regulates the types and characteristics of bulk drug substances and ingredients that may be used in compounding, limits the amount of compounded product that may be distributed out of state, and allows a pharmacy to advertise that they offer "compounding services", but they may not advertise the compounding of any particular drug, class or type of drug.

Access to Health Care Records - 1997 WI Act 157

Wisconsin statute 146.83 concerning access to health care records has been amended to require that health care providers release records directly to a patient's health care provider upon request and with a statement of informed consent. The amendment also prohibits concealing or withholding health care records from a patient's health care provider or to prevent or obstruct an investigation or prosecution. Violations of the statute as amended still include actual damages and exemplary damages along with injunctive relief. This amendment was effective in April 1998. Copies of 1997 WI Act 157 are available from the department or via Internet at <http://www.legis.state.wi.us/billtext/acts/97acts.html>

Tax Delinquency, A New Basis for Denial, Suspension and Revocation

Since 1996, the law has required the department to verify that applicants for credential renewal are not delinquent in payment of Wisconsin state taxes. The department is required to deny renewal if the Department of Revenue certifies that an applicant is tax delinquent.

Effective January 1, 1999, the scope of the law will expand to apply to other state agencies, including the Department of Transportation and the Department of Natural Resources. The law will also change to include applicants for new licenses and current credential holders. After January 1, 1999, the Department of Regulation and Licensing is required to deny the applications for an initial credential if the applicant is certified by the Department of Revenue as being liable for delinquent state taxes. The Department will also be required to revoke the credential of current holders who are tax delinquent.

A person denied or revoked because of a tax delinquency status may request the Department of Revenue to review the certificate of tax delinquency at a hearing.

The text of the new law is in 1997 Wisconsin Act 237 at section 307 and sections 532-551. Act 237 is available in most public libraries and can be viewed on the Internet at <http://www.legis.state.wi.us/billtext/acts/97acts.html>

Administrative Warnings May be Issued Under New Law - 1997 WI Act 139

Examining boards, the department and other regulatory authorities are authorized to issue administrative warnings under the new law effective May 5, 1998. An administrative warning may be issued to close an investigation if a regulatory authority determines that no further action is warranted because the complaint involves a first occurrence of a minor violation and the warning adequately protects the public.

Under the law, an administrative warning puts the professional on notice that if the misconduct is repeated, the incident that was the basis for the warning can be used to prove that the person warned knew the conduct was prohibited. A warning is not discipline and may be issued without a formal complaint or a hearing. The contents of the warning shall be private and confidential.

A credential holder may have a warning reviewed before the department or board that issued the warning. Act 139 requires the department to promulgate rules establishing uniform procedures for administrative warnings. The text of 1997 WI Act 139 is available from the department and can be viewed on the Internet at <http://www.legis.state.wi.us/billtext/acts/97acts.html>

Disciplines

EDWARD G. MEIXNER, R.PH.

MADISON WI

REPRIMAND

Provided a refill to a patient without a consultation. A department investigator observed this transaction and then observed two other patients receive prescriptions from an unlicensed staff person, and without any consultation. Ordered to pay costs of \$150. Effective 6/10/98. Phar 7.01(1)(e) Case #LS9806101PHM.

VAN S. KNUTSON, R.PH.

IRON RIDGE, WI SUSPENDED (indefinitely)

A urine sample of the pharmacist tested positive for metabolites of diazepam. The pharmacy performed an audit and found that it was missing 219 tablets of 5mg. diazepam, and a number of other benzodiazepenes and opiates. He is responsible for taking these missing controlled substances without the permission of his pharmacy employer. He is a regular casual user of marijuana. Also made false statements to the board. His license is suspended indefinitely. He may apply for a stay of the suspension. Also ordered to pay costs. Effective 4/21/98. Secs. 450.10(1)(a)2., 943.20(1), 961.38(3), 961.41(3g), Stats. Phar 8.05(2), 10.03(1), (2) and (8) Case #LS9712091PHM.

KEVIN A. WILLIAMS, R.PH.

WEST ALLIS WI SUSPENDED (at least 5 years)

On or about 11/1/96 he began diverting Percocet, a schedule II drug, from his place of employment for his own personal use. He made a statement to an investigator that he was diverting medications to give to his father and denied any personal use. This statement was false and was known to be false when the statement was made. He also admitted to diverting Tussionex, hydrocodone syrup and Vicodin from a previous employer pharmacy and entered treatment. The board was not aware of this until 1998. Suspended at least five years. He may petition for a stay. Also ordered to pay a forfeiture of \$1,000 and costs of \$200. Effective 6/10/98. Secs. 450.10(1)(a)2. and 3., 450.11(1), (7)(a), (h), 943.20(1)(a) and 961.43(1)(a), Stats. Phar 8.05(2), 10.03(1) and (2) Case #LS9806102PHM.

LOOK DRUG STORE #2

KAUKAUNA WI

REPRIMAND

Routinely permitted more than one unlicensed person per pharmacist to select, count and prepare prefabricated dosage forms for nursing home patients, without obtaining board approval. Routinely permitted nonpharmacists to receive prescription orders via telephone. Routinely stored hard copies of prescription orders for schedule III, IV and V controlled substances with prescriptions for noncontrolled substances without stamping each

with a red "C". Changed managing pharmacist without notifying the board. Ordered to pay costs of \$800 and forfeiture of \$10,000. Effective 5/12/98. Phar 7.01(1)(a) and (3), 6.03, 8.03(3) Case #LS9805121PHM.

LYLE L. VANDENBERG, R.PH.

KAUKAUNA WI

REPRIMAND

Routinely permitted more than one unlicensed person per pharmacist to select, count and prepare prefabricated dosage forms for nursing home patients, without obtaining approval of the board for a higher ratio of pharmacists to auxiliary personnel. Routinely permitted nonpharmacists to receive prescription orders via telephone. Ordered to pay a forfeiture of \$1,000. Effective 4/14/98. Phar 7.01(1)(a) and (3) and 8.03(3) Case #LS9804143PHM.

MARK KOBIN, R.PH.

APPLETON WI

REPRIMAND

Routinely permitted more than one unlicensed person per pharmacist to select, count and prepare prefabricated dosage forms for nursing home patients without obtaining approval from the board for a higher ratio of pharmacists to auxiliary personnel. Routinely permitted nonpharmacists to receive prescription orders via telephone. Ordered to pay a forfeiture of \$1,000. Effective 4/14/98. Phar 7.01(1)(a) and (3), 8.03(3) and 6.03 Case #LS9804141PHM.

MARILYN L. KUHRT, R.PH.

ONALASKA WI SUSPENDED (at least 5 years)

Arrested twice for operating a motor vehicle while influenced by an intoxicant. Her license is suspended for at least 5 years. The suspension is stayed with limitations imposed. Ordered to continue to participate in a rehabilitation, monitoring and treatment program. Effective 4/14/98. Sec. 450.10(1)(a)(3), Stats. Case #LS9804142PHM.

DAVID L. KLEINGARTNER, R.PH.

BLOOMER WI SUSPENDED (at least 5 years)

Diverted noncontrolled and controlled substances for his personal use from his employing pharmacy in 1997. Purchased controlled substances for the pharmacy contrary to policy that the pharmacy would not stock controlled substances. An audit showed diversion of approximately 11,000 dosage units of schedule III and IV controlled substances. Admitted to the DEA to taking acetaminophen with codeine, schedule V codeine cough syrup and long-term usage of butalbital with acetaminophen and carisoprodol. He did not have any legitimate explanation for the presence of these drugs in his home or on his person. Has voluntarily entered

treatment. Suspended at least 5 years, which suspension is stayed for 3 months with limitations imposed. Ordered to pay costs of \$100. Effective 6/10/98. Secs. 450.11(1),(7)(a) and (h), 943.20(1)(a), 961.38(3), 961.41(3g), 961.43(1)(a), Stats. Phar 8.05(2), 10.03(1) Case #LS9806103PHM.

Complaints Against Licensees

Complaints are processed in the following manner:

All complaints received by the Pharmacy Examining Board and the Department are routed to the Division of Enforcement (DOE) where they are logged into the computer and given a number.

Complaints are screened by several board members and the supervisor of the DOE prosecutors and the supervisor of the DOE investigators. The complaint screening process results in a decision to open or not open a complaint for investigation. Sometimes additional information is requested of the complainant at this stage of the process. Most boards are now moving toward screening complaints at least once a month.

If a complaint is opened for investigation, it is assigned to a team in DOE. Teams consist of prosecutors, investigators, legal assistants and, in some cases, auditors. A specific prosecutor and investigator is assigned to the case and the investigator commences an investigation as soon as possible. The investigation generally includes corresponding with the complainant, the credential holder and other people with relevant information. Documents are reviewed and the investigator often interviews people to obtain more information.

A board member is assigned to the case as an advisor. The board member offers suggestions to the investigator and, after the investigation is concluded, the advisor recommends that the case be closed for a certain specified reason or that the case proceed to possible disciplinary action.

If the case advisor recommends possible disciplinary action, a prosecutor reviews the file and requests additional investigation, if needed. The prosecutor usually offers the credential holder an opportunity to agree to a resolution of the matter. The offer may be in the form of a written stipulation for some type of discipline, such as a revocation, suspension, limitation, reprimand, and/or an assessment of all or part of the costs of the investigation and prosecution. If the licensee rejects the stipulation, the attorney schedules a hearing before an administrative law

judge. The hearing is like a trial and the credential holder may have an attorney represent him or her. After the hearing, the administrative law judge prepares a proposed decision and refers it to the Board.

If a case advisor recommends that a case be closed, the case is reviewed by the Board at its next meeting and the Board either concurs or refers the case for disciplinary action. Stipulations and proposed decisions are also referred to the Board for final disciplinary action. If the Board disagrees with a proposed stipulation, the Board may refer the case back to the prosecutor for more negotiations or, possibly, a hearing. If the Board disagrees with a proposed decision of an administrative law judge, it may change parts of the proposed decision, but it will have to explain why it is making the change.

There is considerable due process built into the complaint process. Credential holders or their attorneys are given many opportunities to respond to proposals and to object to decisions. Ultimately, if a credential holder disagrees with the Board's disciplinary decision, the credential holder may appeal the case to Circuit Court.

Letters are sent to complainants and credential holders at various stages in the process, informing them of receipt of a complaint and the final disposition of a complaint.

Department of Regulation and Licensing
Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935

REGULATORY DIGEST

Bulk Rate
U.S. Postage
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RETURN SERVICE REQUESTED

Telephones

Automated phone system for the Health Professions:
(608) 266-2811

- Press 1 Request Application
- Press 2 Name or Address Change
Need a Duplicate License
Request a Letter of Good Standing
- Press 3 Complaint Filing Information
- Press 4 Status of a Pending Application
- Press 5 Verifying Current Status of a Credential
Holder
- Press 6 Repeat Menu Choices

Fax Number

(608) 261-7083

Verifications

ALL verification requests must be in writing. Requests for verifications to other states must be in writing. The cost is \$10. Please make out check or money order to the Department of Regulation and Licensing.

Digest on Web Site

The March 1998 digest is on the web.

Visit the Department's Web Site

<http://badger.state.wi.us/agencies/drl/>
Send comments to dorl@mail.state.wi.us

1998 Board Meeting Dates

September 8, October 14, November 10,
December 8.

Wisconsin Statutes and Code

Copies of the Pharmacy Examining Board Statutes and Administrative Code can be ordered from the Department. Include your name, address, county

and a check payable to the Department of Regulation and Licensing in the amount of \$5.28. The latest edition is dated June, 1998.

Change of Name or Address?

Please photocopy the mailing label of this digest, make changes in name or address, and return it to the Department. Confirmation of changes are not automatically provided.

WIS. STATS. S. 440.11 ALLOWS FOR A \$50 PENALTY TO BE IMPOSED WHEN CHANGES ARE NOT REPORTED WITHIN 30 DAYS.

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